Fluconazole Tablets USP

150 mg

Composition:
Each uncoated tablet contains:
Fluconazole USP.....150 mg
Excipients.....q.s.
Approved color used.

DOSAGE AND ADMINISTRATION
Single dose
Vaginal candidiasis: The recommended dosage of fluconazole for vaginal candidiasis is 150 mg as a single oral dose.
Multiple dose
AS ORAL ABSORPTION IS RAPID AND ALMOST COMPLETE, THE DAILY DOSE OF FLUCONAZOLE IS THE SAME FOR ORAL AND INTRAVENOUS ADMINISTRATION. In general, a loading dose of twice the daily dose is recommended on the first day of therapy to achieve plasma concentrations close to steady-state by the second day of therapy.
The daily dose of fluconazole for the treatment of infections other than vaginal candidiasis should be based on the infecting organism and the patient's response to therapy. Treatment should be continued until clinical parameters or laboratory tests indicate that the active fungal infection has subsided. An inadequate duration of treatment may lead to recurrence of the active infection. Patients with AIDS and cryptococcal meningitis or recurrent oropharyngeal candidiasis generally require maintenance therapy to prevent relapse.
Fluconazole tablets are administered orally. Fluconazole tablets may be taken with or without food.

CONTRAINDICATIONS:
Fluconazole tablets are contraindicated in patients who have demonstrated hypersensitivity to fluconazole or to any of its excipients. There is no information regarding cross-hypersensitivity between fluconazole and other azole antifungal agents. Caution should be exercised when prescribing fluconazole tablets to patients with hypersensitivity to other azoles. Co-administration of other drugs known to prolong the QT interval and metabolized by the CYP3A4 enzyme, such as erythromycin, pimozide, and quinidine, is contraindicated in patients receiving fluconazole.

INDICATIONS AND USAGE:
Fluconazole tablets are indicated for the treatment of:
Vaginal candidiasis (vaginal fungal infections due to *Candida*).
Oropharyngeal and esophageal candidiasis. In open, non-comparative studies involving relatively small numbers of patients, fluconazole tablets were also effective in treating *Candida* urinary tract infections, peritonitis, and systemic *Candida* infections, including candidemia, disseminated candidiasis, and pneumonia.
Cryptococcal meningitis. Before prescribing fluconazole tablets to patients with AIDS and cryptococcal meningitis... No studies comparing fluconazole tablets with amphotericin B in HIV-negative patients have been conducted.
Prophylaxis: Fluconazole tablets are also indicated to decrease the incidence of candidiasis in bone marrow transplant patients receiving cytotoxic chemotherapy and/or radiation therapy.
Specimens for fungal culture and other relevant laboratory studies (serology, histopathology) should be obtained prior to therapy to isolate and identify the causative organisms. Therapy may be initiated before culture results and other laboratory findings are known; however, once these results become available, anti-infective therapy should be adjusted accordingly.

WARNINGS
Hepatic injury: Fluconazole should be administered with caution to patients with hepatic dysfunction. Fluconazole has been associated with rare cases of serious hepatic toxicity, including fatalities, primarily in patients with serious underlying medical conditions. In cases of fluconazole-associated hepatotoxicity, no obvious relationship to total daily dose, duration of therapy, sex, or patient age was observed. Fluconazole-associated hepatotoxicity is usually, but not always, reversible upon discontinuation of therapy. Patients who develop abnormal liver function tests during fluconazole therapy should be monitored for the development of more severe hepatic injury. Fluconazole should be discontinued if clinical signs and symptoms consistent with liver disease develop and can be attributed to fluconazole.
Anaphylaxis: Anaphylaxis has been reported in rare cases.
Dermatologic: Exfoliative skin disorders have been reported during fluconazole treatment. Fatal outcomes have been reported in patients with serious underlying diseases. Patients with deep-seated fungal infections who develop skin rashes during fluconazole treatment should be closely monitored, and the drug discontinued if lesions progress. Fluconazole should be discontinued in patients treated for superficial fungal infections who develop a rash that may be attributable to fluconazole.
Potential for fetal harm: There are no adequate and well-controlled clinical trials of fluconazole in pregnant women. Case reports describe a pattern of distinct congenital anomalies in infants exposed in utero to high doses of maternal fluconazole (400 to 800 mg/day) during most or all of the first trimester. These reported anomalies are similar to those observed in animal studies. If fluconazole is used during pregnancy, or if the patient becomes pregnant while taking the drug, the patient should be informed of the potential risk to the fetus. Effective contraceptive measures should be considered for women of childbearing potential treated with fluconazole 400 to 800 mg/day and should be continued throughout the treatment period and for approximately 1 week (5 to 6 half-lives) after the final dose. Epidemiological studies suggest a potential risk of spontaneous abortion and congenital anomalies in infants whose mothers were treated with a single or repeated 150 mg dose of fluconazole during the first trimester; however, these epidemiological studies have limitations, and these findings have not been confirmed in controlled clinical trials.

PRECAUTIONS:
Some azoles, including fluconazole, have been associated with prolongation of the QT interval on the electrocardiogram. Fluconazole causes QT interval prolongation through inhibition of the rapidly activating delayed rectifier potassium current (Ikr). QT interval prolongation caused by other drugs (such as amiodarone) may be amplified through the inhibition of cytochrome P450 (CYP) 3A4. During post-marketing surveillance, rare cases of QT interval prolongation and torsades de pointes have occurred in patients taking fluconazole. Most of these reports involved seriously ill patients with multiple confounding risk factors, such as structural heart disease, electrolyte abnormalities, and concomitant medications that may have contributed. Patients with hypokalemia and advanced heart failure are at increased risk for life-threatening ventricular arrhythmias and torsades de pointes.
Fluconazole should be administered with caution to patients with these potentially pro-arrhythmic conditions.
Concomitant use of fluconazole and erythromycin has the potential to increase the risk of cardiotoxicity (prolonged QT interval, torsades de pointes) and, consequently, sudden cardiac death. This combination should be avoided.
Fluconazole should be administered with caution to patients with renal dysfunction.
Adrenal insufficiency has been reported in patients receiving azoles, including fluconazole. Reversible cases of adrenal insufficiency have been reported in patients receiving fluconazole.
When driving vehicles or operating machinery, it should be noted that dizziness or seizures may occasionally occur.

OVERDOSE:
There have been reports of fluconazole overdose accompanied by hallucinations and paranoid behavior.
In the event of overdose, symptomatic treatment should be instituted (with supportive measures and gastric lavage if clinically indicated).
Fluconazole is largely excreted in the urine. A 3-hour hemodialysis session reduces plasma levels by approximately 50%. In mice and rats administered very high doses of fluconazole, clinical effects in both species included decreased motility and respiration, ptosis, lacrimation, salivation, urinary incontinence, loss of the righting reflex, and cyanosis; death was sometimes preceded by clonic convulsions.

STORAGE:
Store in a cool, dark, and dry place below 30ºC.

Keep medicines out of the reach of children.

PRESENTATION: A package containing 1 tablet.

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